USSN: 10/698,348
Group Art Unit: 3736
Docket No. 151-P-11706US01

REMARKS

Claims 1 – 28 are pending in this application.

Claims 1, 6, 7, 10, 15, 16, 19, 22, 24, and 27 have been amended.

Claims 1 – 28 have been rejected.

Claims 7, 16, 22, and 27 have been objected to.

Amendments to the claims

Claims 1 and 10 have been amended to clarify the claims by breaking the claims down into two basic steps of 1) determining a location in the esophagus, and 2) anchoring a capsule in the esophagus, and by explicitly adding a sub-step establishing the esophageal location relative to the lower esophageal sphincter. These clarifications are supported by the disclosure in paragraph [32]. No new matter has been added.

Claims 6 and 15 have been amended to clarify that the measuring sub-step relates to the anchoring step in claims 5 and 19, respectively. These clarifications are supported by the disclosure in paragraph [32]. No new matter has been added.

Claims 7, 16, 22 and 27 have been amended to clarify the claims by adding a period, and by deleting a redundant phrase referring to the predetermined distance. No new matter has been added.

Claims 19 and 24 have been clarified by explicitly recite a vacuum source and a structure to anchor a capsule in the wall of the esophagus. Support for this amendment can be in paragraph [31], line 1 ("delivery device 22 [in Fig. 2]"). No new matter has been added.

Objections to the Claims

Claims 7 and 16 have been objected to for omitting a period at the end of the claim, for disclosing an "esophageal location" without establishing an antecedent basis, and for not making clear to what the word "identification" was referring. These

objections have been rendered moot by adding a period, by establishing antecedent basis for the esophageal location in claims 1 and 10, and by deleting the reference to identification. With the amendments to claims 1, 7, 10 and 16, claims 7 and 16 should no longer be objectionable.

Claim 22 has been objected to for omitting a period at the end of the claim, for disclosing an "esophageal location" without establishing an antecedent basis, and for not making clear to what the word "identification" was referring. The omitted period and the issue with the word "identification" have been rendered moot by adding a period and by deleting the reference to identification. The objection to the lack of antecedent basis for the phrase "esophageal location" is respectfully traversed, as claim 19, from which claim 22 depends establishes the antecedent basis for the esophageal location in line 1 of that claim. With the amendments and arguments provided, claim 22 should no longer be objectionable.

Claim 27 has been objected to for omitting a period at the end of the claim and for not making clear to what the word "identification" was referring. These objections have been rendered moot by adding a period and by deleting the reference to identification. With these amendments, claim 27 should no longer be objectionable.

Rejections under 35 U.S.C. § 103

Claims 1 – 5, 8 – 14, 17 – 20, 23 – 25 and 28 have been rejected under 35 U.S.C. § 103(a) for obviousness in light of U.S. Patent No. 5,433,216 ("Sugrue et al '216") in view of U.S. Patent No. 6,285,897 ("Kilcoyne et al '897"), while claims 5, 6, 15, 16, 21, 22, 26 and 27 have been rejected under 35 U.S.C. § 103(a) in light of Sugrue et al '216, Kilcoyne et al, and U.S. Patent No. 4,981,470 ("Bombeck '470"). These rejections are respectfully traversed.

Method claims 1 – 18

Claims 1 and 10 recite a method for determining the location of the lower esophageal sphincter by dynamically positioning the catheter using information derived

from variations in pressure of the gas contained in a lumen inside the catheter. The lumen of the catheter is then used for suction to attach a monitoring device to the wall of the esophagus.

The examiner cited several sections of Sugrue et al '216 as showing this method for determining the location of the lower esophageal sphincter. While Sugrue et al '216, discloses pressure sensing using a balloon catheter (column 13, lines 58 – 68), and that catheter can monitor esophageal pressure and test sphincter seals (column 16, lines 5 – 10), Sugrue et al '216 is limited to "manually applying pressure to a selected location [on the skin of the patient] and monitoring any result in increase in pressure ..." (column 16, lines 65 – 67). Sugrue et al '216 is merely a static pressure monitor, and does not describe a method for dynamically moving the sensor and measuring pressure at various locations as is explicitly recited in independent claims 1 and 10. Sugrue et al '216 does not show, disclose or suggest that the baseline pressure measured in a clinical trial is in any way relevant to determining the location of the lower esophageal sphincter (column 34, lines 66 – 68). Sugrue et al '216 does not show, disclose, or suggest any method for determining the location of the lower esophageal sphincter by passing a distal end of the catheter into the stomach, establishing the lumen pressure, pulling back the distal end from the patient, noting an increase in temperature, and then noting a subsequent decrease in pressure, thereby identifying the upper boundary of the lower esophageal sphincter, nor does it show, disclose or suggest any method for placing a monitoring device anywhere in the patient's body, all of which are described in claims 1 and 10.

Kilcoyne et al '897 describes the use of a catheter to place a monitoring device in the esophagus of a patient. Kilcoyne et al '897 discloses only one method for determining the location of the catheter during the placement of the monitoring device: "The monitor 18 can be constrained within or by a deployment device, such as a catheter, until attachment is visually verified through the endoscope 160 by the physician." (column 7, lines 23 – 26) This is manifestly different from the method described in claims 1 and 10, which do not require the use of an endoscope for visual verification at all. In fact, the present invention obviates the need for visual verification, thereby

eliminating the need for a second object and a second procedure. Kilcoyne et al does not show, disclose or suggest the use of a pressure sensor, nor a method for using a pressure sensor, to determine the location of the catheter within the patient, i.e., passing a distal end of the catheter into the stomach, establishing the lumen pressure, pulling back the distal end from the patient, noting an increase in temperature, and then noting a subsequent decrease in pressure, thereby identifying the upper boundary of the lower esophageal sphincter as explicitly recited in claims 1 and 10. Instead, Kilcoyne et al '897 relies on visual inspection using an endoscope.

Bombeck '470 describes a catheter with a balloon pressure sensor and gradations down the side of the catheter to allow the medical professional to determine how far the catheter has been inserted. However, Bombeck '470 does not show, disclose or suggest a method for using the pressure sensor to dynamically determine the location of the lower esophageal sphincter. Instead, Bombeck '470 describes using the gradation marks on the catheter as a guide to "approximately position the catheter within the body of the patient and to make approximations as to the location of the catheter within the body." (column 4, lines 46 – 50) However, the location of the lower esophageal sphincter may vary from patient to patient, thus requiring an independent determination of location of the lower esophageal sphincter for each patient before the use of the catheter begins, or the readings from the gradations will have no use whatsoever in determining the location of the lower esophageal sphincter. In contrast, claims 1 and 10 recite a method that can be used without adaptation from patient to patient for determining the location of the lower esophageal sphincter, using only the catheter described in claims 1 and 10, and then anchor a capsule to the wall of the esophagus. Bombeck '470 manifestly does not show, disclose or suggest the ability to determine the location of the lower esophageal sphincter using only the catheter by passing a distal end of the catheter into the stomach, establishing the lumen pressure, pulling back the distal end from the patient, noting an increase in temperature, and then noting a subsequent decrease in pressure, thereby identifying the upper boundary of the lower esophageal sphincter, as recited in claims 1 and 10.

Thus, none of Sugrue et al '216, Kilcoyne et al '897 and Bombeck '470 shows, discloses or suggests a dynamic method of determining an esophageal location in the esophagus. Sugrue et al '216 discloses pressing on the patient in order to determine the static location of the catheter. Kilcoyne et al '897 discloses using an endoscope to visually determine the location of the catheter. Bombeck '470 discloses using gradation marks to determine the what length of the catheter has been inserted, but not where the catheter is in the patient precisely. Thus, all three fail to show, disclose or suggest the essential elements of claims 1 and 10, i.e., passing a distal end of the catheter into the stomach, establishing the lumen pressure, pulling back the distal end from the patient, noting an increase in temperature, and then noting a subsequent decrease in pressure, thereby identifying the upper boundary of the lower esophageal sphincter. Further, because all of the documents fail to justify the rejection of claims 1 and 10, no combination of the documents shows, discloses, or suggests the claimed method for using catheter lumen pressure for dynamically determining the location of the lower esophageal sphincter as recited in claims 1 and 10. It is respectfully submitted that the rejections of claims 1 and 10 over Sugrue et al '216, Kilcoyne et al '897 and Bombeck '470 are improper and should be withdrawn.

Claims 2 – 9 and 11 – 18 are dependent on claims 1 and 10, respectively. Because they are dependent claims they incorporate all of he limitations of the claims from which they depend. Because rejection of claims 1 and 10 are improper, it is respectfully submitted that the rejection of claims 2 – 9 and 11 – 18 are also improper and should be withdrawn.

Apparatus claims 19 – 28

The examiner has rejected claims 19 and 24 under 35 U.S.C. § 103(a) as being obvious over Sugrue et al '216, in view of Kilcoyne et al '897 and in further view of Bombeck '470. These rejections are respectfully traversed.

As noted above, Sugrue et al '216 discloses pressure sensing using a balloon catheter (column 13, lines 58 – 68), and that catheter can monitor esophageal pressure

and test sphincter seals (column 16, lines 5 – 10), but does not show, disclose or suggest a structure of the catheter for anchoring a capsule on the wall of the esophagus.

Bombeck '470 discloses a catheter with a balloon pressure sensor and gradations down the side of the catheter to allow the medical professional to determine how far the catheter has been inserted, but, similarly to Sugrue et al '216, does not show, disclose or suggest a structure on the catheter for anchoring a capsule, nor the existence of a structure for determining pressure.

There is nothing in either Sugrue et al '216 or Bombeck '470 that shows, discloses or suggests, a combination with Kilcoyne et al '897. In fact, neither Sugrue et al '216 or Bombeck '470 have any reason to combine the elements of their apparatus that with elements of Kilcoyne et al '897. Sugrue et al '216 describes using sensors on the catheter as a temporary monitoring device for internal pressure and pH levels, and therefore would have no reason to need to attach an object to the esophagus, such as is described in Kilcoyne et al '897. Likewise, Bombeck '470 describes using the catheter as a temporary monitoring device for internal pressure and pH levels, and would have no reason to need to attach an object, such as is described in Kilcoyne et al '897. Therefore, one of ordinary skill in the art would have no reason to combine either Sugrue et al '216 or Bombeck '470 with Kilcoyne.

Kilcoyne et al '897 discloses the use of a catheter to place a monitoring device in the esophagus of a patient, but does not show, disclose, or suggest any structure useful for determining the location of the catheter except through the use of an endoscope. There is nothing in Kilcoyne et al '897 to show, disclose, or suggest a combination with either Sugrue et al '216 or Bombeck '470. Kilcoyne has no reason to combine with elements of either Sugrue et al '216 or Bombeck '470. Kilcoyne et al '897 describes using the catheter only to place objects in the esophagus using a separate endoscope, and thus would have no reason to include a pressure sensor, as is described in Sugrue et al '216 and Bombeck '470. In addition, if the addition of a pressure sensor on their catheter was obvious, surely the inventors of Kilcoyne et al '897 would have done so, thereby obviating the need for a different, entirely separate endoscope; this would have saved

money and made the catheter easier and safer to use, which is what is accomplished by the apparatus recited in claims 19 and 24. In addition, both Sugrue et al '216 and Bombeck '470 were earlier in time than Kilcoyne et al '897, and thus were available to Kilcoyne at the time of the filing date of Kilcoyne et al '897. If the combination of Kilcoyne et al '897 with Sugrue et al '216 or Bombeck '470 was obvious then Kilcoyne et al '897 would have used a pressure measurement structure. Instead, Kilcoyne et al '897 teaches away from Sugrue et al '216 and Bombeck '470 by teaching using an endoscope.

It is respectfully submitted that the examiner is using hindsight reconstruction of the sort that the Court of Appeals for the Federal Circuit rejected in *In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000). Without claims 19 and 24 in front of them, a person of ordinary skill in the art would not know to combine Sugrue et al '216 or Bombeck '470 with Kilcoyne et al '897. The unique combination of the present invention results in a catheter that allows for faster procedures, improved safety and comfort of the patient, more accurate results and allows a medical professional to do with one catheter what formerly required two catheters to accomplish. It is respectfully submitted that the rejection of claims 19 and 24 under 35 U.S.C. § 103 over Sugrue et al '216, in view of Kilcoyne et al '897, and in view of Bombeck '470 is improper and should be withdrawn.

Claims 20 – 23 and 25 – 28 are dependent on claims 19 and 24, respectively. Claims 20 – 23 and 25 – 28 contain all of the limitations of claims 19 and 24, respectively. Because the rejections of claims 19 and 24 under 35 U.S.C. § 103(a) are improper, it is respectfully submitted that the rejection of claims 20 – 23 and 25 – 28 are improper and should be withdrawn.

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Summary

In view of the amendments and arguments presented, claims 1 – 28 should be allowable. This application should be in condition for allowance and a notice to that is earnestly solicited.

Respectfully Submitted,

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